<u>IN THE UNITED STATES PATENT AND TRADEMARK OFFIC</u>

plicants:

M.J. Corey et al.

Attorney Docket No.: MICC11888

arlication No.: 10/071,350

Group Art Unit: 1627

February 8, 2002

Examiner: R.J. Gitomer

Title:

METHODS AND COMPOSITIONS FOR COUPLED

LUMINESCENT ASSAYS

# INFORMATION DISCLOSURE STATEMENT

## TO THE COMMISSIONER FOR PATENTS:

Applicants are aware of the information listed in the attached form that may be material to the prosecution of the above-identified patent application.

- Copies of the listed patents, publications, and other information are enclosed for X the Examiner's use.
- Pursuant to 37 C.F.R. § 1.97(b), this Information Disclosure Statement is being 2. X filed before the mailing date of a first Office Action on the merits.
- 3. The Commissioner is hereby authorized to charge any fees which may be required to Deposit Account No. 03-1740. This authorization also hereby includes a request for any extensions of time of the appropriate length required upon the filing of any reply during the entire prosecution of this application. A copy of this document is enclosed.

Respectfully submitted,

CHRISTENSEN O'CONNOR JOHNSON-KINDNESSPLLC

Registration No. 26.997 Direct Dial No. 206.695.1718

I hereby certify that this correspondence is being deposited with the U.S. Postal Service in a sealed envelope as first class mail with postage thereon fully prepaid and addressed to the U.S. Patent and Trademark Office, P.O. Box 2327, Arlington, VA 22202, on the below date.

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TION CITED BY APPLICANTS THAT MAY BE MATERIAL TO THE 2002

PROSECUTION OF THE SUBJECT APPLICATION

MICC118884

Applicants:

Application No.: 10/071,350

Group Art Unit: 1627

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METHODS AND COMPOSITIONS FOR COUPLED

LUMINESCENT ASSAYS

## **U.S. PATENT DOCUMENTS**

None.

## FOREIGN PATENT DOCUMENTS

*Examine Initial	r Cite No.	Document No.	Kind Code	Publication Date (mm/dd/yyyy)	Country	English Abstract Translation Provided Provided
	F1	WO 98/28437	A1	07/02/1998	WIPO	
	F2	11-290096		10/26/1999	Japan	X
	F3	WO 00/75167	A2	12/14/2000	WIPO	

## OTHER INFORMATION

(Including Author, Title, Date, Pertinent Pages, Etc.)

*Examiner	Cite	
Initial	No.	
	O1	Bradbury, D.A., et al., "Measurement of the ADP:ATP Ratio in Human Leukaemic Cell Lines Can Be Used as an Indicator of Cell Viability, Necrosis and Apoptosis," <i>Journal of Immunological Methods</i> 240:79-92, 2000.
	O2	Corey, M.J., et al., "A Very Sensitive Coupled Luminescent Assay for Cytotoxicity and Complement-Mediated Lysis," <i>Journal of Immunological Methods</i> 207:43-51, 1997.
	O3	Crouch, S.P.M., et al., "The Use of ATP Bioluminescence as a Measure of Cell Proliferation and Cytotoxicity," <i>Journal of Immunological Methods</i> 160:81-88, 1993.

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1 6 2002 5	TECH OF
MARK OFFICE O4	Kasatori, N., et al., "Cytotoxicity Test Based on Luminescent Assay of Alkaling Phosphatase Released From Target Cells," <i>Rinsho Byori 42</i> (10):1050-1054, October 1994, retrieved from <i>NCBI.gov</i> , <a href="http://www.ncbi.nlm.nih.gov:80/entrez/query.fcgi?cmd+Retrieve&amp;db=PubMed&amp;list_uids=7996714&amp;dopt=Abstract">http://www.ncbi.nlm.nih.gov:80/entrez/query.fcgi?cmd+Retrieve&amp;db=PubMed&amp;list_uids=7996714&amp;dopt=Abstract</a> [retrieved August 2, 2002].
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O6	Miska, W., and R. Geiger, "A New Type of Ultrasensitive Bioluminogenic Enzyme Substrates," <i>Biol. Chem.</i> 369:407-411, May 1988.
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O8	Olesen, C.E.M., et al., "Novel Methods for Chemiluminescent Detection of Reporter Enzymes," <i>Methods in Enzymology 326</i> :175-192, 2000.
O9	Sasamoto, H., et al., "Chemiluminescent Assay of Alkaline Phosphatase Using Phenacyl Phosphate," <i>Analytica Chimica Acta 306</i> :161-166, 1995.
O10	Schäfer, H., et al., "A Highly Sensitive Cytotoxicity Assay Based on the Release of Reporter Enzymes, From Stably Transfected Cell Lines," <i>Journal of Immunological Methods</i> 204:89-98, 1997.
O11	Ximenes, V.F., et al., "Facile Chemiluminescent Method for Alkaline Phosphatase Determination," <i>Analytica Chimica Acta 402</i> :99-104, 1999.
Examiner	Date Considered

\*Examiner: Initial if reference considered, whether or not citation is in conformance with M.P.E.P. § 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicants.

DKS/KBB:skg/ctg



## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:

Camilla A. Santos, Jules S. Jacob, Benjamin A. Hertzog, Gerardo P. Can

and Edith Mathiowitz

Serial No.:

10/146,184

Art Unit:

1616

Filed:

May 15, 2002

Examiner:

Not Yet Assigned

For:

METHODS AND COMPOSITIONS FOR ENHANCING THE BIOADHESIVE

PROPERTIES OF POLYMERS USING ORGANIC EXCIPIENTS

Assistant Commissioner for Patents Washington, D.C. 20231

#### INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to 37 C.F.R. §1.56 and 37 C.F.R. §1.97, Applicants submit an Information

Disclosure Statement, including five (5) pages of Form PTO-1449. All of the documents cited below were cited by or submitted to the Patent Office in Application Serial No. 09/729,529, filed December 4, 2000, to which the present application claims priority. Pursuant to 37 C.F.R. §1.98(d), Applicants are not enclosing copies of these publications. Copies will be provided upon request, however.

This Information Disclosure Statement is being filed under 37 C.F.R. § 1.97(b) prior to a first Office Action on the merits. It is believed that no fee is required with this submission. However, should a fee be required, the Commissioner is hereby authorized to charge any required fees to Deposit Account No. 50-1868.

U.S.S.N.: 10/146,184 Filed: May 15, 2002

INFORMATION DISCLOSURE STATEMENT

## U.S. Patents

μ.			
Number	Issue Date	<u>Patentee</u>	Class/Subclass
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2,677,700	05-04-1954	Jackson, et al.	260/488
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		Research Foundation	

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U.S.S.N.: 10/146,184
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REFORMATION DISCLOSURE STATEMENT

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MIKOS, et al., "Interaction of Polymer Microspheres with Mucin Gels as a Means of Characterizing Polymer Retention on Mucus," J. Colloid & Interface Sci., 143(2):366-73 (1991).

U.S.S.N.: 10/146,184 Ned: May 15, 2002

RMATION DISCLOSURE STATEMENT

PARK, et al., "Alternative Approaches to Oral Controlled Drug Delivery: Bioadhesives and In-Situ Systems", Recent Advances in Drug Delivery Systems (Anderson & Kim, eds.)

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U.S.S.N.: 10/146,184 Filed: May 15, 2002

FORMATION DISCLOSURE STATEMENT

#### Remarks

This statement should not be interpreted as a representation that an exhaustive search has

been conducted or that no better art exists. Moreover, Applicants invite the Examiner to make an independent evaluation of the cited art to determine its relevance to the subject matter of the present application. Applicants are of the opinion that their claims patentably distinguish over the art referred to herein, either alone or in combination.

Respectfully submitted,

PatrealL. Pabst

Reg. No. 31,284

Dated: September 13, 2002

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U.S.S.N.: 10/146,184 Filed: May 15, 2002

FORMATION DISCLOSURE STATEMENT

## Certificate of Mailing under 37 C.F.R. § 1.8(a)

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September 13, 2002

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•	. 6	3	INFORMATION DISCLOSURE
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on Number 10	10/146,184		
te Ma	y 15, 2002		
ned Inventor Ca	amila A. Santos		
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				U.S. PATENT DOCU	MENTS	
Examiner Cite Initials* No.1		US Patent Document		Name of Patentee or Applicant of Cited Document	Date of Cited Document MM-DD-YYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
			Code 2 known)			
		2,675,619		Cone	04-20-1954	
		2,677,700		Jackson, et al.	05-04-1954	
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		3,535,307		Moss, et al.	10-20-1970	
		3,829,506		Schmolka, et al.	08-13-1974	
		4,757,128		Domb, et al.	07-12-1988	
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		4,938,763	1	Dunn, et al.	07-03-1990	
		4,976,968	1	Steiner	12-11-1990	
		4,997,904		Domb	03-05-1991	
		5,019,400		Gombotz, et al.	05-28-1991	
		5,173,298		Meadows	12-22-1992	

				F	OREIGN PATENT DOCUMEN	ITS		
Examiner Initials*	Cite No.1	Foreign Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM- DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	7°	
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		EP	0 333 523	A2	UAB Research Foundation	09-20-1989		
		wo	91/06286		Enzytech, Inc.	05-16-1991		
		wo	91/06287		Enzytech, Inc.	05-16-1991		
		wo	92/11871	-	Allergan, Inc.	07-23-1992		
		wo	93/21906		Brown University Research Foundation	11-11-1993		
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<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

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Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number CH CELLER 1000 Substitute for form 1449A/PTO Complete if Known INFORMATION DISCLOSURE **Application Number** 10/146,184 STATEMENT BY APPLICANT (use as many sheets as necessary) Filing Date May 15, 2002 First Named Inventor Camila A. Santos 1616 Group Art Unit **Examiner Name BU 107 DIV CON CIP Attorney Docket Number** Sheet 3 of

		OTHER ART NON PATENT LITERATURE DOCUMENTS	
Examiner's Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, cit and/or country where published	T <sup>2</sup>
		BECK, et al., "A new long-acting injectable microcapsule system for the administration of progesterone," Fertil. & Steril., 31(5):545-55 (1979).	
		BENITA, et al., "Characterization of Drug-Loaded Poly(d, Flactide) Microspheres," J. Pharm. Sci., 73(12):1721-24 (1984).	
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		EDELMAN, et al., "Perivascular and intravenous administration of basic fibroblast growth factor: Vascular and solid organ deposition," <i>Proc. Natl. Acad. Sci.</i> , USA <u>90</u> :1513-17 (1993).	
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	•	HARADA, et al., "Basic fibroblast growth factor improves myocardial function in chronically ischemic porcine hearts," <i>J. Clin. Invest.</i> , 94(2):623-30 (1994).	· · · · · · · · · · · · · · · · · · ·
		HOROWITZ, M., "Mucopolysaccharides and glycoproteins of the alimentary tract," <u>Handbook of Physiology</u> (C.F. Code, ed.), pp. 1063-85 (American Physiological Society 1967).	
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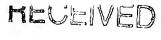
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<sup>1</sup> Unique citation designation number 2 See attached Kinds of U.S. Patent Documents, 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. Applicant to place a check mark here if English language Translation is attached.



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V.	MARKEDIA	<b>&gt;</b>			First Named Inventor	Camila A. Santos	
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					Examiner Name		
	Sheet	4	of	5	Attorney Docket Number	BU 107 DIV CON CIP	

		OTHER ART NON PATENT LITERATURE DOCUMENTS	
Examiner's Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, cit and/or country where published	Τ²
		LABHASETWAR, et al., "Sotalol Controlled-release systems for arrhythmias: <i>In vitro</i> characterization, <i>in vivo</i> drug disposition, and electrophysiologic effects," <i>J. Pharm. Sci.</i> , <u>83</u> (2):156-164 (1994).	
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		MIKOS, et al., "Interaction of Polymer Microspheres with Mucin Gels as a Means of Characterizing Polymer Retention on Mucus," <i>J. Colloid &amp; Interface Sci.</i> , 143(2):366-73 (1991).	
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		SMART, et al., "An in vitro investigation of mucosa-adhesive materials for use in controlled drug delivery," <i>J. Pharm. &amp; Pharmacol.</i> , 36:295-99 (1984).	
		SPIRO, R., "Glycoproteins," <i>Annual Review of Biochemistry</i> , 39:599-638 (Snell, ed. 1970).	

Examiner's	Date Considered	
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<sup>&</sup>lt;sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language Translation is attached.

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					Filing Date	May 15, 2002	
					First Named Inventor	Camila A. Santos	
					Group Art Unit	1616	
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<sup>&</sup>lt;sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language Translation is attached.

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Camila A. Santos
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Examiner Initials*	Cite No.1		cument and Code <sup>2</sup> if known)	Name of Patentee or Applicant of Cited Document	Date of Cited Document MM-DD-YYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
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